REMARKS/ARGUMENTS

This Amendment and Response comprises the Applicants' reply to a non-final Office Action having a mailing date of October 26, 2007. Claims 1-13 are currently pending in this application, with Claims 1-5 having been withdrawn from consideration. No new matter has been added. Thus, Claims 6-13 are currently pending. As set out more fully below, reconsideration and withdrawal of the rejection of Claims 6-13 and a notice of allowance of all pending claims are respectfully requested.

Rejection of Claims 6-12 under 35 U.S.C. § 112 - Indefiniteness

The Examiner contends that the term "wild type GT gene" is unclear since it fails to particularly point out what it means. However, generally, the term "wild-type" does not refer to mutations, and is a term that is widely used in specifications and in theses. Therefore, one of ordinary skill in the art would have obviously considered the term "wild type GT gene" as equivalent to a term "GT gene" (material evidence attached).

Therefore, Applicants do not believe that the term "wild type GT gene" is unclear. Further, it may be considered as equivalent to the "GT gene", and thus the amendment from "wild type GT gene" to "GT gene" in the specification may be within the scope of permissible amendment.

The Examiner contends that the term "a normal GT protein" is indefinite. In response to the Examiner's contention, Applicants have amended the claim to recite "a GT protein" by deleting the word "normal", and accordingly, believe that the amendment fully addresses the problem at issue.

The Examiner points to the unclear nexus between the limitation "homologous recombination" occurring at DNA level and the limitation "to suppress expression of a normal GT protein" at protein level.

"Suppressing the expression of the GT gene", which the Examiner mentions later, is generally referred to using the expression "knock down" rather than "knock out". That is, knockdown refers to a technique of reducing the amount of expression of genes by degradation of

mRNA that is expressed using RNAi. In contrast, knocking out refers to a technique of causing a defect in a part of a target gene using homologous recombination.

In the present invention, a vector having a knocked out GT gene is prepared to disrupt the GT gene through the homologous recombination. Therefore, judging based on the third step described in the specification (Construction of a Gene Targeting Vector Carrying a Knocked Out GT Gene and Introduction of the Vector into Nuclear Donor Cells), the phrase "to suppress expression of a normal GT protein" of the present invention obviously refers to knocking out the GT gene through the homologous recombination, and its nexus is clear as well. That is, it is clear that the present invention aims to partially knock out the GT gene to suppress the expression of a GT protein rather than the expression of the GT gene. Therefore, Applicants believe the Examiner's contention is inappropriate.

The Examiner contends that "a promoter trap method" is unclear. Since Applicants agree with the Examiner's opinion, and have deleted Claim 8, it is believed the amendment fully addresses the problem at issue.

Rejection of Claims 6-13 under 35 U.S.C. § 112 - Enablement

In response to the Examiner's rejection, Applicants have amended term of "a somatic cell line" into term of "a fetal fibroblast cell" to further specify the cell type, and believe that the rejection may be overcome as a result of the amendment.

The Examiner contends that the claims are rejected based on lack of guidance in how to use the claimed heterozygous knockout pig due to xenotransplantation caused by hyperacute xenograft rejection, and its manufacturing method is not disclosed in the specification, and thus are not able to be carried out.

As pointed out by the Examiner, when organs of a heterozygous knockout pig are transplanted into a human, the immune system of the human operates to recognize the pig's organs as antigens, and this causes the hyperacute xenograft rejection. Therefore, the Examiner's rejection is somewhat reasonable.

However, the purpose of the present invention is to produce live offspring carrying a knocked out GT gene. Also, obtaining the homozygous knockout pig corresponds to one aspect of the present invention. Therefore, if one of ordinary skill in the art produces live offspring carrying a knocked out GT gene and obtains a homozygous knockout pig through mating the produced live offspring based on the specification and the drawings of the present invention, the rejection based on lack of enablement may be overcome.

Meanwhile, a method for manufacturing a heterozygous knockout pig and a homozygous knockout pig using homologous recombination is a technique that is generally known to one of ordinary skill in the art to which the invention pertains. That is, a targeting vector (a carrier carrying a gene to a desired location) is manufactured, and the vector is introduced into the pig's cell to obtain a chimeric pig via the homologous recombination process. Afterward, the heterozygous and homozygous knockout pigs can be obtained through germ line transmission. The claims are rejected based on lack of enablement, since the germ line transmission is not described in detail. Therefore, the germ line transmission will be described below in detail. A targeting vector is injected into an embryonic stem cell to select a clone that has undergone successful homologous recombination. Then, the clone is mixed with blastocysts of normal pigs to produce chimeric pigs. This is described in the detailed description of the invention of the present invention. When the produced chimeric pig is mated with a normal pig, F1 pigs (heterozygous knockout pigs) can be produced, and when the F1 pigs are mixed with each other, homozygous knockout pigs can be produced. This is a method for obtaining the heterozygous and homozygous knockout pigs through the germ line transmission. The obtaining method is well-known to one of ordinary skill in the art, and since the method for manufacturing the chimeric pig is described in the original specification in detail to enable one of ordinary skill in the art to embody the claimed invention, even though a method for manufacturing a homozygous knockout pig is not described, the present invention does not seem lack of enablement.

The Examiner points to the enablement rejection of the claims based on the absence of disclosure of exon 9 sequences to determine the Ava I –Dra III fragment. However, in the original specification of the present invention, GeneBank Accession Number of the pig GT gene is indicated

rather than exon 9 sequences. That is, in Example 3 of the original specification, the GeneBank Accession Number of the pig GT gene exon 9 sequence (AF221517) as well as its length are (3.9kb) are described. In addition, as the Examiner mentioned, the base sequence at which Ava I and DraIII restriction enzyme is operated and cut is well-known. Therefore, one of ordinary skill in the art would have easily determined sequences of exon 9 based on the GeneBank Accession Number, and according to the sequences, there is only one region where the restriction enzyme, Ava I-DraIII can be operated and cut. Therefore, even though the sequences of exon 9 are not described, since the region where Ava I-DraIII restriction enzyme of exon 9 can be operated is clear, the sequences of the fragment are clear as well. Therefore, Applicants believe that the rejection based on lack of enablement is inappropriate.

The Examiner contends that Claims 11 and 12 fail to comply with the requirements for deposit of biological materials. That is, the deposited biological material recited in Claims 11 and 12 is insufficient to enable one of ordinary skill in the art to readily reproduce, and thus the claims fail to comply with the requirements for deposit of biological materials.

However, in the present invention, every necessary matter for implementing the present invention is described in detail through exemplary embodiments.

That is, Claim 11 is described in Examples 1 to 4 and 6 to 9 in the specification. In addition, in the Argument in response to the Office Action, the scope of the claims is further specified to easily embody the claimed invention based on the exemplary embodiments.

Furthermore, Claim 12 is described in Examples 12 to 14 in the specification, and thus the exemplary embodiments are sufficient to enable one of ordinary skill in the art to easily embody the claimed invention. Moreover, the amendment filed in response to the Office Action further narrows the scope of Claim 12, and thus the exemplary embodiments are sufficient to enable one of ordinary skill in the art to embody the claimed invention.

Rejection of Claims 6-13 under 35 U.S.C. § 112 - Written Description

The Examiner contends that although there is expected to be variation among the species of cDNA, which encode the GT gene, this is not described in the detailed description of the invention, and thus Claims 6 and 13 are rejected.

Accordingly, in response to the Examiner's contention, Applicants cancel Claims 6-8 without prejudice or disclaimer of the subject matter thereof, amend Claim 9, and cancel Claim 13 without prejudice or disclaimer of the subject matter thereof. That is, Applicants amended "isolating an alpha-1,3-galactosyltransferase (GT) gene clone from a pig genomic BAC library" in Claim 6 to recite "isolating an alpha-1,3-galactosyltransferase (GT) gene clone from a pig genomic BAC library through a polymerase chain reaction (PCR) using primers prepared based on a pig GT cDNA sequence (GeneBank Accession No.: AF221517)". That is, in the present invention, the PCR is carried out using the primers prepared based on the pig GT cDNA sequence (GeneBank Accession No.: AF221517) and pig genomic DNA to obtain a positive signal, so that accuracy of the primers and the PCR are verified, and the pig genomic BAC library are screened by the PCR, so that a GT gene clone is isolated. Therefore, the GT gene, for which protection is sought in the present invention, is defined to be isolated using the primers prepared based on the pig GT cDNA sequence (GeneBank Accession No.: AF221517), and this is described in Step 2 (Isolation of GT Gene) and Example 2 of the specification in detail. Further, Applicants believe that the amendment may be made within the scope of permissible amendment, and thus the grounds for rejection are inappropriate.

In view of the above amendments and arguments, Applicants respectfully request that the Examiner favorably consider the claims as amended and place the present case in a condition for allowance. In the event a telephonic interview with undersigned counsel would facilitate this objective, Applicants' counsel kindly requests the courtesy of a telephone interview and can be reached directly at 303-863-2977.

Respectfully submitted,

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